UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,557	02/10/2004	Peter Nash	C150.12.4	1455

7590 09/02/2009

Richard O. Bartz
Suite 350
6750 France Avenue South
Edina, MN 55435

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
09/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,557	NASH ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-10 and 42-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-10 and 42-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed May 19, 2009 has been entered. Claims 1, 10, 42, 48-49, 53-54 and 58 have been amended. Claims 2-4, 6, 11-41, 43-44 and 59-60 are canceled.

Election/Restrictions

2. In view of applicants' amendments to claim 54, claims 54-58 will be examined in this Office Action.

3. Claims 1, 5, 7-10, 42 and 45-58 are under consideration in this office action.

Request for Information

4. Applicant refers to the results of the invention being predicated on the inhibitors' binding characteristics as described in the paper entitled "Natural Solutions for Animal Agriculture". The paper filed August 11, 2008 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office. There is no citation information associated with this paper and the paper is not listed on the IDS submitted May 30, 2008. Therefore the paper has been placed in the application file, but the information referred to therein has not been considered. Thus it is requested that Applicant provide the appropriate citation data, including the date.

Withdrawal of Rejections

5. The objection of claim 49 is withdrawn in view of applicants' amendments and arguments.

6. The rejection of claims 10, 48 and 53 under 35 U.S.C. 112, second paragraph have been withdrawn in view of applicants' amendments and arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 49-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The rejection is on the grounds that neither the specification nor originally presented claims provides support for a microbial adherence inhibitor or method of producing the inhibitor for administration to swine to prevent the adherence of or inhibit the ability of colony-forming organisms in the respiratory tract of a swine selected from the group of respiratory organisms consisting of swine influenza (H1N1, H3N2), *Pasteurella multocida, Pasteurella haemolytica, Mycoplasma haemolytica, Mycoplasma*

hypopneumoniae, Haemophilus suis, Haemophilus somnus, Haemophilus parasuis and *Haemophilus planopneumonia* in the respiratory tracts of said animals.

Response to Arguments

8. Applicant's arguments filed May 19, 2009 have been fully considered but they are not persuasive.

The new matter rejection of claims 49-58 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants' point to original claims 3, 13, 17, 28-30, 40 and 44 for support. However the original claims only recite that the targeted colony- forming immunogen is from the class of respiratory bacteria including *P. Multicoda, M. haemolytica, H. somnus,* and *H. suis.* It is noted, that the use of the bacterium is not equivalent to the production of an inhibitor that prevents adherence of the organism. Therefore is no teaching for inhibiting the ability for the instantly recited organisms to adhere to the respiratory tract. Additionally, there is no recitation of *P. haemolytica, H. parasuis* and *H. planopneumonia*. Applicants' point to [0004] for support, however the paragraph merely states common causation agents of swine respiratory diseases can include *H. parasuis, H. planopneumonia*, and Pasteurella haemolytica. There is no disclosure of a microbial inhibitor inhibiting adherence of the bacterium. Paragraphs [0005-0007 and 0051-0052] fail to even recite any of the recite organisms or the inhibitors ability. Paragraph [0053] states that respiratory complexes such as *Pasteurella multocida, M. haemolytica, H. somnus,* swine influenza viruses *and Mycoplasma* bacteria must

posses the capability of sticking or adhering to the surface of the mucus membrane in order to multiply. *Therefore,* Applicant did not point to support in the specification for a microbial adherence inhibitor or method of producing the inhibitor for administration to swine to inhibit the adherence of colony-forming organisms such as swine influenza (H1N1, H3N2), *P. multocida, P. haemolytica, M. haemolytica, M. hypopneumoniae, H. suis, H. somnus, H. parasuis* and *H. planopneumonia* in the respiratory tracts of said swine produced by the method. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of a microbial adherence inhibitor that inhibits the adherence of the organisms. Thus, there appears to be no teaching of a microbial adherence inhibitor that inhibits the adherence of the organisms. Applicant has not pointed to any pages of the instant specification and claims for support of the amendment drawn to the microbial adherence inhibitor that inhibits the adherence of the organisms. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of a microbial adherence inhibitor that inhibits the adherence of the organisms as recited by the amendments. Therefore, the claims incorporate new matter and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 5, 7-9, 42, 45-47, 49-52 and 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US Patent 5,367,054) in view of Okuno et al., (US Patent 6,337,070).

Lee teaches the eggs are produced by bringing the subjects to a state of hyperimmunization by means of primary immunization with specific antigens, such as viral antigens (col. 7, lines 50-56). Lee teaches antigens such as *Haemophilus influenza* and *Diplococcus pneumoniae* as respiratory organism for which immunoglobulins can confer resistance in order to confer immunization against (col. 8, lines 17-31). Lee teaches the egg produced by the animals in the hyperimmune state and immune eggs (col.7, lines 60-63). Lee teaches taking eggs from a hyperimmune avian animal (col. 7, lines 48-50). In summary, Lee teaches the selection of antigens; sensitization of animals by primary immunization; administering boosters of antigens of appropriate dosage to induce and maintain the hyperimmune state; and collecting the eggs from the animal during the hyperimmune state (col. 8, lines 7-15). Lee states that the repeated immunizations are given at intervals over a suitable period of time to hyperimmunize the animal (col. 8, lines 33-40). Lee teaches using avian animals including poultry, chickens, turkeys, geese, ducks and caged birds (col. 4, lines 2-4). Lee teaches using the purified egg yolk immunoglobulins, mainly IgY, IgA and IgM from immune egg yolk (col. 3, lines 35-37). Lee teaches a variety of means of separation wherein the eggs are collected, cracked and the egg is then subjected to purification (see example1). Lee teaches that the product is useful for pharmaceutical purposes such as immunization (col. 3, lines 38-40). Lee et al., teach drying the protein fraction from a de-salted

fraction, thereby mixing the antibody contents with a dry carrier material (example12). However, Lee does not teach inoculating the birds with respiratory viruses comprising swine influenza (H1N1, H3N2).

Okuno et al., teach inoculation with respiratory viruses such as swine influenza (H1N1, H3N2). Okuno et al., teach that influenza viruses H1N1 and H3N2 subtypes of the virus (col1, lines 25-30). Okuno et al., teach the need for antibodies takes having cross-recognizing ability for influenza virus A virus subparticles and has a virus neutralization activity (col.2, lines 22-25). The antibody recognizes regions of the H1N1, H2N2 and H3N2 (col. 5, lines 27-32). The antibody inhibits membrane fusion activities and markedly neutralizes the infectious powers of these virus strains and is usable in the prevention and treatment of influenza (col. 6, lines 59-65). It is well known in the art that people get sick from avian-human influenza viruses generated in pigs because pigs have vectors for both avian and human receptors, thus there is a need prevent interspecies transmission. Okuno et al., teach the need for a safe vaccine (col.2, lines 20-22). Okuno et al., the antibody may be formulated into a variety of preparations (col. 6-7, lines 59-6).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate inoculation with respiratory viruses comprising swine influenza (H1N1, H3N2) as taught by Okuno et al., to the microbial adherence inhibitor and method of Lee in order to have antibody containing contents that have cross-recognizing ability for influenza virus A virus subparticles. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention since Lee teach the desire to produce IgY, IgA and IgM antibody containing products using for pharmaceutical applications for the treatment of other animals. Furthermore, one having ordinary skill in the art would have been motivated to do this because Lee and Okuno et al., teach primary immunization with specific antigens, such as viral antigens or those of respiratory organisms. Finally it would have been prima facie obvious to combine the invention of Lee and Okuno et al., to advantageously achieve virus neutralization activity and protection against infectious viral illness in animals.

Response to Arguments

10. Applicant's arguments filed May 19, 2009 have been fully considered but they are not persuasive.

Applicants argue that Lee does not disclose a method of producing a microbial adherence inhibitor by inoculating female birds, with swine influenza (H1N1, H3N2). In response to applicant's arguments against the Lee reference individually, one cannot show nonobviousness by attacking reference individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is agreed that while Lee does teach inoculating birds with virus, Lee does not teach inoculating the birds with swine influenza (H1N1, H3N2). However, Okuno et al., teach inoculation with respiratory viruses such as swine influenza (H1N1, H3N2). Okuno et al., also teach the need producing antibodies having cross-recognizing ability

for influenza virus A virus subparticles because the antibodies have viral neutralization abilities. Therefore applicants' argument is not persuasive.

Applicants assert that Lee does not disclose allowing a period of time to permit the production in the bird of antibody-containing contents in the bird's eggs. However, contrary to Applicants assertion, Lee clearly states that the repeated immunizations are given at intervals over a suitable period of time to hyperimmunize the animal (col. 8, lines 33-40). Lee also teaches the hyperimmune state can be induced and maintained be repeated booster administrations at fixed time intervals and that booster administration is optimal (see col. 8, lines 10-13 and lines 53-60). Therefore Lee clearly teach a time period to permit the production in the bird of antibody containing contents in the eggs.

Applicants urge that Lee does not disclose isolating IgM and IgA immunoglobulins from the egg albumin. Contrary to Applicants statement, Lee teaches using the purified egg yolk immunoglobulins, mainly IgY, IgA and IgM from the immune egg (col. 3, lines 35-37). Therefore Lee teaches isolating or purifying IgM and IgA.

Applicants assert that Lee does not disclose creating a microbial adherence inhibitor that binds to a respiratory organism, such as swine influenza (H1N1, H3N2), in the respiratory tract of a swine to reduce the ability of the respiratory organism to multiply in the respiratory tract of the swine. However, Lee teach passive immunization is an alternative method of protection from infection, since antibodies are safe, natural products and oral vaccine containing specific immunoglobulins would alleviate the

problems associated with antibiotics. Lee also teach providing antibody containing contents from eggs in order to confer immunization against respiratory organisms. Lee teaches the purified products are used for pharmaceutical purposes such as passive immunization. Therefore Lee does disclose creating a microbial adherence inhibitor, such as an immunoglobulin that binds to a respiratory organism in order to confer immunization, thereby reducing the number of organisms.

Furthermore, product by process claims drawn to a microbial adherence inhibitor (i.e, antibody-containing contents from eggs) are not limited to the manipulations of the recited steps (even though Lee discloses those steps), rather it is the structure (the antibody containing contents from eggs) that is implied by those steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.

However the product is the same or obvious from the product of the prior art, thus the instant claims are not patentable and applicants' arguments are not persuasive.

In this case, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Lee teach the desire to produce IgY, IgA and IgM antibody containing products using for pharmaceutical applications for the treatment of other animals. Moreover, it would have been *prima facie* obvious to combine the invention of Lee and Okuno et al., to advantageously achieve virus neutralization activity and protection against infectious viral illness in animals because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art the time of the invention.

Applicants argue that Okuno et al., do not disclose inoculating female birds to produce a microbial adherence inhibitor using antibody-containing contents from the bird's eggs. In response to applicant's arguments against the Okuno et al., reference individually, one cannot show nonobviousness by attacking reference individually where the rejections are based on combinations of references. See *In re Keller*; *In re Merck & Co*. In this case, Lee teach inoculating female birds to produce a microbial adherence inhibitor using antibody-containing contents from the bird's eggs. Therefore applicants' argument is not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

11. Claims 1, 5, 7-9, 42, 45-47, and 49-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Okuno et al., (US Patent 6,337,070).

Tokoro teaches a method of producing a microbial adherence inhibitor and the microbial adherence inhibitor for administration to animals to substantially prevent the adherence of targeted colony-forming immunogens in the respiratory tracts of said animals produced by the method of: A. Inoculating hens, in their egg laying age, with a targeted colony-forming immunogen (col. 5, lines 29-31); B. Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming immunogen (col. 5, lines 47-52); C. Harvesting the eggs laid by the birds (col. 5-6, lines 67-1); D. Separating the antibody-containing contents of said eggs from the shells (col.6, lines 8-12). The antigens used to immunize hens include pollens, bacteria, viruses, molds, allergens, or a combination of antigens (col. 4, lines 50-57). The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food for animal to prevent adherence of the targeted immunogen (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The specific antibody-containing substances may be the specific antibody isolated from the overall ovum, yolk or albumen of the egg (col. 3, lines 60-64). Tokoro teaches the yolk being separated from the egg since the yolk contains most of the antibodies (col. 6, lines 10-12). Tokoro states that specific antibodies against some antigens are primarily

present in the albumen of the egg, thus the albumen can be used in the production method. Additionally, both the yolk and albumen of each egg are used in the production method (col. 6, lines 10-16). However, Tokoro does not teach inoculating the birds with respiratory viruses comprising swine influenza (H1N1, H3N2).

Okuno has been discussed above as teaching inoculation with respiratory viruses comprising swine influenza (H1N1, H3N2).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate inoculation with respiratory viruses comprising swine influenza (H1N1, H3N2) as taught by Okuno et al., to the microbial adherence inhibitor and method of Tokoro in order to have antibody containing contents that have cross-recognizing ability for influenza virus A virus subparticles. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Tokoro teach using viral or bacterial immunogens, as the targeted colony forming immunogens, along with the desire to produce antibody containing products useful for the treatment of other animals. Furthermore, one having ordinary skill in the art would have been motivated to do this because Tokoro teach primary immunization with specific antigens, such as bacterial or viral antigens. Finally it would have been prima facie obvious to combine the invention of Tokoro and Okuno et al., to advantageously achieve virus neutralization activity and protection against infectious respiratory swine influenza pathogens.

Response to Arguments

12. Applicant's arguments filed May 19, 2009 have been fully considered but they are not persuasive.

Applicants assert that there is no disclosure in Tokoro of an IgY immunoglobulin that binds to colony-forming illness-causing immunogens. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., an IgY immunoglobulin that binds to colony-forming illness-causing immunogens are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that the only claims 1 and 42 recite IgY when referring to allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the colony-forming organism selected from the group of respiratory organisms swine influenza (H1N1, H3N2), said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs. Tokoro teaches allowing a sufficient amount of time to permit the production of antibody content within the eggs yolk and albumin. There is no recitation of IgYs binding ability contrary to Applicants assertion.

Applicants urge that Tokoro does not provide a teaching or a method for reducing or eliminating the incidence of illnesses caused by a colony-forming organism selected from a group of respiratory organisms consisting of swine influenza (H1N1, H3N2) by

binding egg IgY immunoglobulins combined with IgM and IgA immunoglobulins to the colony-forming respiratory organisms to reduce the ability of the respiratory organisms to multiply in the respiratory tracts of swine. In response to applicant's argument that the Tokoro reference fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e a method for reducing or eliminating the incidence of illnesses caused by a colony-forming organism selected from a group of respiratory organisms consisting of swine influenza (H1N1, H3N2) by binding egg IgY immunoglobulins combined with IgM and IgA immunoglobulins to the colony-forming respiratory organisms to reduce the ability of the respiratory organisms to multiply in the respiratory tracts of swine are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Independent claims 1 and 49 are drawn to a microbial adherence inhibitor; while claims 42 and 54 are drawn to a method of producing a microbial adherence inhibitor. There are no claims a method for reducing or eliminating the incidence of illnesses caused by a colony-forming organism selected from a group of respiratory organisms consisting of swine influenza (H1N1, H3N2) by binding egg IgY immunoglobulins combined with IgM and IgA immunoglobulins to the colony-forming respiratory organisms to reduce the ability of the respiratory organisms to multiply in the respiratory tracts of swine; therefore applicants argument is not persuasive. It is agreed that Applicants' claimed method is not a treatment of a disease in animals.

In response to applicant's argument that about the use of IgY , IgA and IgM immunoglobulins, a recitation of the intended use of reducing the ability of the

respiratory organisms to multiply in the respiratory tracts of swine of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, there is no structural difference between the antibody-containing contents of the eggs or immunoglobulins isolated and purified by Tokoro when compared to the antibody-containing contents of the eggs recited by the claims. Therefore the argument is not persuasive. Furthermore Tokoro is not limited to the treatment of intestinal diseases, since Tokoro states that the substances are useful in the treatment of various infectious diseases other then intestinal diseases (col. 4, lines 17-20).

Applicants argue that Tokoro does not coat a dry feed carrier with a mixed egg yolk and albumin product as defined in Claims 7, 10, 45, 47 and 48. The reference microbial adherence inhibitor such as dried egg antibody is used as an additive to food or milk for animal to prevent adherence of the targeted immunogen (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). Tokoro teaches the separated antibody-containing egg yolk was produced as a powder, homogenized as directly spray dried into a powder which does not cause significant loss of the activity of the antibody using conventional techniques (col. 6, lines 20-35). The specific antibody containing substance is used as additives in foods for livestock and poultry, (col. 6, lines 48-50). Livestock food is well known to be dry, thus the food is a dry carrier and milk is a carrier material. The rejection does not rejection claims 10 or 48, therefore applicants'

argument is not persuasive. Therefore Applicants arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

13. Claims 8-10, 46-48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US Patent 5,367,054), Okuno et al., (6,332,070) and Coleman (US Patent 5,585,098) further in view of Ishihara et al., (US Patent 6,068,862).

The rejection is on the grounds that Lee, Okuno et al., Coleman and Ishihara et al., teach methods drawn to a mixing and pasteurization step; a storage step; and carrier material being distilled dried grains or dried beet pulp.

Response to Arguments

14. Applicant's arguments filed May 19, 2009 have been fully considered but they are not persuasive. The rejection of claims 8-10, 46-48 and 53 under 35 U.S.C. 103(a) as being unpatentable over Lee (US Patent 5,367,054), Okuno et al., (6,332,070) and Coleman (US Patent 5,585,098) further in view of Ishihara et al., (US Patent 6,068,862) is maintained for reasons already of record.

Applicants argue that the is no disclosure in Ishihara et al., or Coleman of the antibody containing contents associated with a dry carrier as defined in claims 7, 9-10, 45 and 47-48. Ishihara et al., teach dried grains as carrier material which is mixed with the microbial adherence inhibitor antibody (col. 5, lines 30-35, and Examples 9 and 10). Ishihara et al., teach feed for poultry including grains such as corn feed, and wheat bran; while feed for dairy cows contains grains such as corn, rye and wheat bran

(Examples 9 and 10). The animal feed additive is a specific antibody that specifically binds to an infectious microorganism or virus is produced from chicken egg antibodies obtained from eggs of egg laying hens hyperimmunized with infectious microorganisms or viruses (col. 5, lines 30-35). Thus Ishihara et al., teach dried grains as a dry carrier material for antibody-containing contents from eggs. One having ordinary skill in the art would have been motivated to do this because the Ishihara et al., teach the animal feed additives being mixed with carrier the materials of animal feed improves intestinal functions, feed efficiency and eliminates malodor. Therefore applicants argument is not persuasive and the rejection is maintained.

Claim Objections

15. Claims 53 is objected to because of the following informalities:

a) Claim 53 is dependant upon claim 53. Appropriate correction is required.

New Grounds of Objection and Rejection Necessitated by Amendments

Claim Objections

16. Claim 58 is objected to because of the following informalities: Claim 58 recites "The microbial inhibitor according to claim 54…" however claim 54 is drawn to a method of production and not to the inhibitor. Therefore appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 recites the antibody-containing contents of the eggs are "…stored for subsequent administration to the swine by spraying or squirting the antibody containing contents…" It is unclear what additional steps the claim is attempting to add to the production method. It is also unclear how storage for administration is achieved if the antibody-containing contents are sprayed or squirted in the respiratory tract or the swine. Therefore clarification is required to overcome the rejection.

Conclusion

18. No claims allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645